

REMARKS

Office action summary. The Examiner has set forth a restriction requirement requiring election between Group I, claims 1-17, and Group II, claims 18-21. Claims 1-17 have been examined based on a tentative election said to have been made by Mr. Huston.

Claims 10 and 14 are rejected as indefinite. Claims 1-17 are rejected as obvious over U.S. Patent 6,743,211 ("Prausnitz"). Claims 1-17 are rejected for obviousness-type (nonstatutory) double patenting over U.S. Patent No. 6,663,820 (the patent of which this application is a divisional).

These rejections are overcome by the amendments herein and otherwise traversed.

Claim amendments. Claim 2 has been amended to correct an antecedent basis problem. Claim 10 has been amended to correct the dependency. Claim 14 has been amended to correct antecedent basis problems.

Restriction requirement. The tentative election made by Mr. Huston is confirmed without traverse and without prejudice to presenting claims 18-21 in a divisional of this application. However, Mr. Huston is no longer of record in light of the power of attorney filed November 11, 2005.

Indefiniteness rejections. It is believed that the amendments to claims 10 and 14 correct the indefiniteness problems noted by the Examiner.

Obviousness-type double patenting rejection. This application is a divisional of U.S. Patent 6,663,820, in which the Office made two restriction requirements. Under 35 USC § 121, in divisionals resulting from restriction requirements, obviousness-type double patenting rejections over the parent are generally not permitted. See, e.g., MPEP § 804.01. The Examiner has not explained why any exception to 35 USC § 121 would apply here. It is consequently believed that the obviousness-type double patenting rejection over U.S. Patent No. 6,663,820 is not well taken.

Obviousness rejection. The Examiner rejects all examined claims, including all dependent claims, over Prausnitz. The Examiner particularly points to col. 19, lines 1-13; col. 21, line 49 through col. 22, line 5; col. 22, lines 51-52¹; col. 23, lines 39-64. These passages

¹ The indicated lines do not contain a complete sentence and thus it is believed that the Examiner may have miscited them.

describe different processes, and it is not clear how the Examiner believes they would be modified to fall within the scope of the pending claims.

MPEP § 2142 lists three criteria, all of which must be met in order for there to be a *prima facie* case of obviousness:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Examiner has failed to meet the requirements for a *prima facie* case of obviousness over the Prausnitz reference. Prausnitz does not teach or suggest modifying the microneedle manufacturing processes disclosed therein in order to arrive at a process which includes either making a microneedle structured out of patterned photoresist as required by claim 1, or use of soft lithography as required by claims 9 and 11. The Examiner also does not explain why a person of skill in the art would have a reasonable expectation of success in either separating the patterned photoresist to create a microneedle structure from the photoresist material (claim 1) or in the incorporation of soft lithography (claims 9 and 11) in any of Prausnitz's processes.

As the Examiner notes, Prausnitz "lacks a clear teaching of separating the patterned photoresist from the substrate (as recited in claim 1) to make the microneedle structure and the aspect of coating the patterned photoresist with a moldable material and allowing the moldable material to harden 'using a soft lithography procedure' as required in claims 9 and 11." (Office Action at 4-5.) The Examiner's entire discussion of why a person of skill in the art would have been motivated to modify the teachings of Prausnitz to meet those limitations is as follows:

Given the state of the art and the overall disclosure of Prausnitz et al, such would have been clearly obvious features. It surely would have been obvious form [sic] Prausnitz et al to employ a resist made mold and simply peeled this off from the substrate to form an initial microneedle array (mold) and soft lithography – ie microcontact printing² – is quite well known in the art and would have been an obvious modification over injection molding.

² Contrary to what the Examiner appears to believe, soft lithography encompasses considerably more than microcontact printing. See, e.g., Younan Xia and George M. Whitesides, Soft Lithography, Annu. Rev. Mater. Sci. (1998) 28:153-84 (submitted concurrently with this response).

The Examiner does not state any reason why the person of skill in the art would want to make a mold or a microneedle array out of photoresist rather than epoxy, the material out of which Prausnitz actually suggests making molds in the passages on which the Examiner relies.

The Examiner does not say why one of skill in the art would expect that “simply peeling” crosslinked photoresist off from the substrate would preserve the delicate, micro-sized features of the patterned photoresist. This is particularly curious in light of Prausnitz’s preference, in the passage (col. 21, line 49 through col. 22, line 5) relied on by the Examiner, for using a sacrificial layer to achieve the separation of epoxy. If Prausnitz takes the trouble to use and then wet-etch away a sacrificial layer for micro-patterned epoxy (which one would generally expect to be more robust than crosslinked photoresist), a person of skill in the art following Prausnitz would see little expectation of success with simple peeling.

The Examiner also does not explain how it is that microcontact printing can substitute for injection molding as recited in the passages relied on from Prausnitz. The two processes would seem to have different objectives. Note in particular the following description of microcontact printing: “It uses the relief pattern on the surface of a PDMS stamp to form patterns of self-assembled monolayers (SAMs) on the surfaces of substrates by contact. Microcontact printing differs from other printing methods in the use of self-assembly (especially, the use of SAMs) to form micropatterns and microstructures of various materials.” Younan Xia and George M. Whitesides, “Soft Lithography,” *Annu. Rev. Mater. Sci.* (1998) 28:153, 159. Thus, microcontact printing is a method for placing a monolayer on a surface, in contrast to injection molding which is generally a method for creating a three-dimensional object using heat and pressure to cause the material of which the object is made to fill a mold.

In sum, the Examiner has not established a *prima facie* case of obviousness for the claims which are being rejected as obvious.

Conclusion. If the Examiner has any questions about this response it is respectfully requested that he telephone the undersigned attorney at his direct dial (650) 251-7712.

Respectfully submitted,

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